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10/538,589	04/28/2006	Thomas J Smith	112981.125US1	9056
23483	7590	09/25/2009	EXAMINER	
WILMERHALE/BOSTON			YOUNG, MICAH PAUL	
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BOSTON, MA 02109			PAPER NUMBER	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/538,589	<b>Applicant(s)</b> SMITH, THOMAS J	
	<b>Examiner</b> MICAH-PAUL YOUNG	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/28/06, 6/15/05</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 6/15/05 and 6/28/06 was filed after the mailing date of the Specification on 4/28/06. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 9-20, 24-30, 34-42, and 45-46 are rejected under 35 U.S.C. 102(b) as being anticipated by Hettche et al (USPN 5,271,946 hereafter '946).

The '946 patent teaches a sustained release pharmaceutical dosage form comprising a multiplicity of particles coated with a sustained release polymer (abstract, col. 3, lin. 10-15). The dosage form can be administered via a suspension of the coated particles (col. 3, lin. 22-26, col. 3, lin. 58-61). The core particle comprising the active agent is coated with a polymer solution comprising alkylcellulose polymers that can be both hydrophilic and hydrophobic such as ethylcellulose and hydroxypropylcellulose (col. 3, lin. 65-col. 4, lin. 35). The coated cores are further coated with semi-permeable coating comprising alkylcellulose polymers (col. 4, lin. 26-45). The second coating is semi-porous comprising porous and non-porous areas (col. 5, lin. 65-

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col. 6, lin. 28). The second polymer coating comprises pore forming agents (col. 6, lin. 30-60). The first coating is present in a concentration from 0.1-200 % of the core drug particles (col. 5, lin. 1-8). The coatings are sprayed as a solution to the core drug particle (col. 4, lin. 40-51). The coating may also be applied via a dip coating method such as coacervation method (col. 4, lin. 52-53). The particles once coated comprise carriers and auxiliary components (col. 9, lin. 10-38)

Regarding the release kinetics of the coated particles it is the position of the Examiner that these limitations do not overcome the prior art since the '946 patent teaches a coated particle made with the same components as the instant claims. The release kinetics are an inherent functional limitation of the composition, falling from the arrangement of the compositional components. Since a composition and its properties cannot be separated, and the coated particles of the '974 patent have identical components, the coated particles must also have the same properties.

Regarding the manner in which the core particle is coated, claims 18 and 19, it is the position of that these limitations do not overcome the prior art since the process limitations render the claims product by process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

For these reasons the claims are rejected.

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Claims 1-4, 6, 9-19, 24, 25, 27-31, 34-42, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Paradissis et al (USPN 5,133,974 hereafter '974).

The '974 patent teaches a sustained release formulation comprising coated core particles comprising a drug and a second coating applied to the core, wherein the coated particles exhibit a zero order release of the drug (abstract). The core particle comprises a drug coated to a sugar sphere (col. 4, lin. 12-20). The drug coated sphere is sprayed with a solution comprising a first binding polymer including cellulose, vinyl and acrylic based polymers (col. 5, lin. 40-45). These polymers include hydrophilic polymers such as hydroxypropylmethylcellulose of hydrophobic polymers such as ethylcellulose (*Ibid.*). The coated drug sphere is further coated with second polymer comprising a film forming agent that forms a sustained release particle (col. 6, lin. 67-col. 7, lin. 10). These film forming agents include cellulose derivates (*Ibid.*). The second polymer can comprise pore-forming agents present in the coating layer (col. 7, lin. 10-15). These pore-forming agents comprise 25% of the layer, meaning there are portions of the layer that are porous and non porous. These particles once coated have a size of at least 250 microns (col. 7, lin. 22).

Regarding the release kinetics of the coated particles it is the position of the Examiner that these limitations do not overcome the prior art since the '974 patent teaches a coated particle made with the same components as the instant claims. The release kinetics are an inherent functional limitation of the composition, falling from the arrangement of the compositional components. Since a composition and its properties cannot be separated, and the coated particles of the '974 patent have identical components, the coated particles must also have the same properties.

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Regarding the manner in which the core particle is coated, claims 18 and 19, it is the position of that these limitations do not overcome the prior art since the process limitations render the claims product by process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

For these reasons the claims are rejected.

Claims 1-4, 6, 9-12, 16-19, 24, 27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Hendrickson et al (USPN 5,286,497 hereafter ‘497).

The ‘497 patent teaches a sustained release formulation comprising multiple coated beads that exhibit zero-order release of an active agent (abstract, Figures). The beads comprise a core bead that is formed from compression (col. 6, lin. 10-16). The core comprises the drug and comprises a binding solution coated to the drug in order to keep the drug in place (col. 5, lin. 20-25). The binder solution comprises cellulose, vinyl and acrylic based polymers (col. 5, lin. 25-35). The coated drug core is further coated with a second polymeric coating comprising an acrylic based polymer (col. 6, lin. 10-50). The coated beads have a size range from 354-595 microns (col. 4, lin. 50-55).

Regarding the release kinetics of the coated particles it is the position of the Examiner that these limitations do not overcome the prior art since the ‘497 patent teaches a coated particle

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made with the same components as the instant claims. The release kinetics are an inherent functional limitation of the composition, falling from the arrangement of the compositional components. Since a composition and its properties cannot be separated, and the coated particles of the '497 patent have identical components, the coated particles must also have the same properties.

Regarding the manner in which the core particle is coated, claims 18 and 19, it is the position of that these limitations do not overcome the prior art since the process limitations render the claims product by process claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

For these disclosures render the claims anticipated.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 6-8 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Paradissis et al (USPN 5,133,974 hereafter '974).

As discussed above the '974 patent discloses a sustained release formulation comprising coated core drug particles comprising an active agent, a first cellulose coating and a second coating. The cores of the '974 patent start out at 74 microns and are coated and sieved with a -10+60 mesh sieve, meaning that some particles sieved through the screen will have dimensions less than 2000 (-10 mesh) microns but the majority will be smaller and as small as 250 (60 mesh) microns. Of these particles it would have been obvious to seek smaller particles since smaller particles would have an increased surface area when administered, increasing the total amount of pharmaceuticals administered to the patient.

With these things it would have been obvious to select the smaller particle sizes of the '974 patent in order to product a dosage form with increased surface area, and a better chance of active agent transmission. One of ordinary skill in the art would have been motivated to modify the prior art as described with an expected result of a dosage form useful for sustained release.



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Claims 1, 21-23 and 48-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Hettche et al (USPN 5,271,946 hereafter '946).

As discussed above the '946 patent discloses a sustained release formulation comprising coated core particles comprising a first and second polymeric coating, where the first polymeric coating is present in a concentration from 0.1-200% of the weight of the core particle. The reference is however silent to the % volume of the core particle. The reference also differs from the instant claims by not reciting the specific ranges of the instant claims. These modifications and differences would have been obvious to one of ordinary skill in the art and appear to be merely an optimization of ranges arrived at by routine experimentation. The general conditions of the claims have been met, namely a core particle comprising a drug that is coated with a polymeric material that is up to 200% of the weight of the core particle. It would have been obvious to optimize these concentrations in order to control the release rate of the coated drug particles. More polymer would slow the release while less polymer would increase the release rate. These optimizations would result from routine experimentation and would be obvious. Also regarding the reporting of the percentage volume as relative to the core particle, it is the position of the Examiner that these ranges would also be obvious to optimize. The same general conditions have been met by the '946 patent, and as such the optimization of these general conditions would also be obvious to one of ordinary skill in the art as a result of routine experimentation.

Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

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Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

One of ordinary skill in the art would have been motivated to optimize the ranges recited in the instant claims in order to better optimize and control the release of the coated drug cores. By increasing or decreasing the concentration of the first coating polymer the release of the drug can be either increased or decreased and prolonged over time. It would have been obvious to optimize these components with an expected result of a stable formulation with a precise controlled release.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Friday 8:00-5:30; every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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